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RUNNING HEAD: Systematic Review of RCTs for Obese Adults with Risk Factors

Behavioural interventions for obese adults with additional risk factors for morbidity:

Systematic review of effects of on behaviour, weight and disease risk factors

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1 ABSTRACT

2 **Background:** Reducing obesity through effective behaviour change interventions is of
3 key importance to prevent disabling and life-threatening conditions, particularly in
4 individuals already at risk for morbidity.

5 **Purpose:** To assess the effects of behavioural interventions for obese adults with
6 additional risk factors for morbidity on behaviour, weight and disease risk factors.

7 **Methods:** Systematic review of randomised controlled trials (RCTs). Three electronic
8 databases and three journals were searched for behavioural interventions (aimed at
9 changing dietary intake and/or physical activity [PA]) for adults (mean BMI $\geq 30 \text{ kg/m}^2$;
10 mean age ≥ 40 years) with risk factors for morbidity, reporting follow-up data ≥ 12
11 weeks.

12 **Results:** Forty-four RCTs met the inclusion criteria. Behavioural outcomes, weight
13 loss, and cardiovascular disease risk factors showed consistent modest improvements
14 over time, especially for interventions targeting both diet and PA.

15 **Conclusion:** Behavioural interventions in at-risk populations showed positive effect
16 tendencies on behaviour, weight and disease risk factors. However, there is still ample
17 room for improvement and future research should focus on identifying the most
18 effective means of inducing dietary and PA behaviour change in this vulnerable
19 population.

20

21 INTRODUCTION

22 The prevalence of obesity worldwide is both high and increasing [1] . Obesity is
23 associated with numerous comorbidities, including cardiovascular disease, type 2
24 diabetes, hypertension, and certain cancers [2]. Behavioural interventions, aimed at
25 influencing peoples' dietary and/or PA behaviour, lead to weight loss and improved
26 obesity-related risk factor profiles in individuals with excess weight [3-5].

27 When studying obesity interventions, it is important to consider the influence of
28 additional risk factors for morbidity¹ as interventions in individuals carrying these risk
29 factors may be less effective [3]. Clinically obese populations with additional risk
30 factors are one of the fastest growing patient populations. Consequently, it is
31 paramount to develop an understanding of the effects of behaviour change intervention
32 on behaviour, weight and risk factor indicators in this population [6].

33 Previous systematic reviews evaluating the effects of behavioural interventions
34 paid little attention to the most proximal target of behavioural weight-loss interventions,
35 behaviour change itself [7]. As some intervention studies may not achieve significant
36 weight loss or improvement in health risk factors, information about behavioural change
37 is not only relevant but essential to our appraisal of the intervention. Few systematic
38 reviews examine the effectiveness of behaviour change interventions on behaviour,
39 although evidence shows that dietary advice was found to lead to significant positive
40 changes in self-reported fibre, fruit and vegetable, and saturated fat intake [8] and
41 interventions promoting PA showed a significant moderate effect on self-reported PA
42 [9]².

43 This systematic review extends the evidence base for behavioural obesity
44 treatment by addressing the lack of behavioural analysis in the scrutiny of intervention
45 effectiveness, and focuses attention on a population in need of intervention: obese
46 adults with additional risk factors for morbidity.

47 METHODS

48 **Objectives**

49 To review the effects of behavioural interventions for obese adults with at least one
50 additional risk factor for morbidity on behaviour (diet and PA), weight and risk factors.
51 The effect of interventions on outcomes were compared for intervention groups (which

¹ For further discussion of additional risk factors, see Mokdad et al. 2003[73]

² For the purpose of this review dietary intake and PA are considered examples of behaviours.

52 focused on changes in diet only, PA only, or both diet and PA) against control or less
53 intensive intervention groups.

54 **Study inclusion criteria**

55 *Types of studies.* Published RCTs providing ≥ 12 weeks follow-up data after
56 randomisation. No language limitations were specified.

57 *Types of participants.* Individuals with a mean/median BMI ≥ 30 kg/m². Studies
58 focused on adult obesity with a mean/median age of ≥ 40 as there is a rapid increase in
59 obesity-related diseases including the metabolic syndrome [10] and type 2 diabetes [11]
60 in middle age. At least one additional risk factor for morbidity was required as this
61 population is in greatest need of behaviour change to prevent long-term morbidity.

62 *Types of interventions.* Behavioural interventions aimed at changing diet and/or PA.
63 For this review, interventions are classified by ‘diet only (D-only),’ ‘PA only (PA-
64 only),’ or ‘diet and PA (D-PA)’.

65 *Types of outcome measures.* The outcomes examined in this review were behaviour
66 (i.e. objective or self-reported measures of diet and/or PA), weight and risk factors (total
67 cholesterol, low density lipoprotein [LDL] cholesterol, high density lipoprotein [HDL]
68 cholesterol, triglycerides, systolic and diastolic blood pressure [SBP and DBP],
69 glycosylated haemoglobin [HbA1c] and fasting plasma glucose [FPG]).

70 **Search strategy for identification of studies**

71 Three electronic databases (MEDLINE, EMBASE, and PsycInfo) were searched for
72 relevant studies using a comprehensive search strategy (available upon request). Three
73 journals (International Journal of Obesity, International Journal of Behavioural
74 Medicine and Obesity Research) were searched by hand. Reference lists of relevant
75 review articles and of all included studies were searched for further studies.

76 **Methods of the review**

77 *Identification of RCTs.* The first 200 references of RCTs were independently screened
78 by two researchers (AA and SUD) and differences were resolved in discussion.
79 Thereafter, the identification of studies was completed by one researcher (SUD).

80 *Quality assessment of studies.* Standard criteria for RCTs were used to appraise the
81 methodological quality [12].

82 *Data extraction.* Three researchers (AA, FFS and SD) extracted data for an initial three
83 studies, and differences were resolved by discussion. Thereafter, one researcher (SUD)
84 extracted data for behaviour, weight and risk factors from the remaining studies.

85 Behavioural variables were assessed by a wide variety of measures (Table 1).
86 Most studies focused on altering kilocalorie and fat intake, so these two outcomes
87 became the main dietary focus. These measures are a proxy for change in dietary
88 behaviour and used as dietary behavioural outcomes for the purpose of the current
89 review. All data entry into meta-analytic software, Review Manager (Version 4.2), was
90 double checked one month after initial entry.

91 *Statistical analysis.* Where possible, a meta-analysis of the data was undertaken to
92 determine the overall effect size. Two different effect sizes were calculated depending
93 on the outcomes under scrutiny [13]. Dietary fat and PA outcomes were assessed as
94 standardised mean differences (SMDs), equivalent to Hedge's adjusted g , as both
95 outcome variables were reported on a variety of scales (see Table 1). Kilocalorie,
96 weight and disease risk factor outcomes were reported on the same scales and were
97 combined as mean differences (MDs). Change scores for dietary fat, kcal and PA
98 outcomes were preferred and meta-analyses used a mixture of change from baseline and
99 final value scores [13]. Weight and disease risk factor outcomes were analysed as
100 change scores, and missing data was imputed using methods previously described [12].

101 Ninety-five percent confidence intervals (CIs) were derived for effect sizes.
102 Degree of inconsistency across studies was assessed using I^2 [14]. I^2 levels of $\geq 25\%$
103 and $\geq 50\%$ were interpreted as an indicator for moderate and substantial heterogeneity
104 respectively. It should be noted that I^2 is dependent on the number of primary studies
105 included and, in this case, there are some examples in which there are only a few
106 primary studies. I^2 levels $\geq 50\%$ were interpreted as an indicator for substantial
107 heterogeneity. Random effects methods for combining data were used reflecting the
108 high heterogeneity in many of the meta-analyses. Intention-to-treat data were used
109 wherever available [13].

110 -----Table 1 -----

111 RESULTS

112 ----- Figure 1 -----

113 **Overall description of studies**

114 Forty-four studies met inclusion criteria (Table 1).

115 *Participants.* The mean age of participants was 55.0 ($SD = 6.8$) and the mean BMI was
116 33.1 ($SD = 2.2$) ranging from 30.1 [15] to 38.8 [16]. In studies including participants of
117 both genders, a small majority of women was reported (55%); eleven studies sampled
118 women exclusively, and one study only men [17]. The majority of studies ($n=21$)

119 examined individuals with type 2 diabetes. Others included individuals with risk
120 factors such as hypertension ($n=4$), impaired glucose tolerance ($n=3$), or cardiovascular
121 disease ($n=2$) (see Table 1 for details). Two studies used the same intervention for two
122 different populations and were treated as separate studies [18, 19]. The mean number of
123 participants was 240 ($SD = 502$) ranging from 26 [20] to 3234 [21] with a mean dropout
124 at completion of 16% ($SD = 10.2$).

125 *Intervention setting.* Most studies were conducted in the USA ($n=27$). Other countries
126 were Canada ($n=5$), United Kingdom ($n=5$), the Australia ($n=4$), Finland ($n=2$) and
127 Holland ($n=1$).

128 *Study Designs.* Twenty-seven trials allowed for comparison between a D-PA
129 intervention against a usual care (UC) or waiting list control (WLC) group. Six
130 comparisons between D-only and six comparisons of PA-only against UC or WLC
131 group were possible. Altogether, seven trials for D-PA and four for D-only
132 interventions allowed comparison of more intensive against less intensive treatments.
133 Interventions were categorised as more intense when the behaviour change components
134 within the intervention were delivered more frequently in one of two intervention
135 groups. Similarly, if one intervention utilised more intervention components compared
136 with the other it was classified as more intensive.

137 *Intervention duration and intensity.* The modal duration of interventions was 6 months
138 ($n=12$), ranging from 2 [22, 23] to 36 months [24]. The modal duration of follow-up
139 was 12 months ($n=15$) ranging from 3 [25] to 36 months [24]. Outcomes were
140 commonly reported at distinct points in time - 3, 6, 12, 24, and 36 months - and
141 intervention effects are summarised for these time points. Where there were results
142 reported for different time, these were ascribed to the nearest time point of common
143 reporting.

144 Intensity of contact varied in intervention arms ranging from one contact every
145 four months [26] to twice weekly [27]. The average contact per month was 4.6 ($SD =$
146 6.5). High intensity contact interventions tended to be exercise classes.

147 *Behavioural recommendations.* Recommendations regarding dietary intake were
148 categorised using Avenell et al.'s (2004) classifications. Out of 51 different dietary
149 treatment arms within the included trials, 20 provided general healthy eating advice³, 18
150 used a 600 kcal/day deficit or low fat reducing diet, 9 used a low calorie diet (1000-

³ This includes studies where participants could choose their own healthy eating goals.

151 1600 kcal/day), two study arms used the Weight Watchers diet⁴, two provided no
152 details, and one used the Ornish diet² (Table 1).

153 PA recommendations varied in intensity, type, duration, frequency, and energy
154 expenditure, and intensity was typically moderate. Few interventions reported
155 recommending a particular type of activity, with those that did favouring walking and
156 regular daily activities. The recommended activity duration was generally between 30-
157 45 minutes, three to four times per week. Some recommendations specified targets for
158 energy expenditure within a given period of time. Many studies employed supervised
159 exercise classes and groups (Table 1).

160 **Quality of trials**

161 *Randomisation.* Nineteen trials were identified as having made a good attempt at
162 concealment of randomisation. The remaining 25 studies stated that allocation was
163 random without giving descriptions of procedures.

164 *Description of withdrawals.* Twenty-one studies provided numbers and reasons for
165 study participant dropout and 20 studies mentioned the numbers of withdrawals only.
166 Three studies stated withdrawals only but did not provide further details.

167 *Intention to treat.* Twenty-five studies claimed to use intention-to-treat (ITT) data
168 analysis, and 13 studies did not state ITT procedures. In six studies descriptions
169 remained ambiguous.

170 *Blinding of outcome assessors.* The majority of trials ($n=32$) did not report blinding of
171 outcome assessors. Three studies stated that assessors were blinded, but did not provide
172 further detail. Nine studies that stated blinding assessors and described the blinding
173 procedures.

174 **Behaviour change**

175 -----Table 2-----

176 *Diet and PA Interventions vs. Usual Care/Waiting List Control.* Fifteen studies [21, 24,
177 26-32, 36, 39-41, 45, 46] reported kilocalorie intake which allowed for meta-analysis at
178 3, 6, 12, 18, 24 and 36 months (Table 3). Reported decreases in favour of intervention
179 compared with control groups were found at all time points and significant MDs were
180 detected at 12, 18 and 36 months. Evidence of heterogeneity in trial effects (i.e.
181 differences in outcomes) was detected at 3 ($I^2 = 46.6\%$) and 6 ($I^2 = 65.4\%$) months.
182 Most studies reported outcomes at 6 and 12 months. Three out of 8 studies [30, 45, 46]

⁴ It was felt that Weight Watchers and Ornish diets did not fit within the Avenell et al. (2004) categories.

183 reported significant differences in kilocalorie intake between intervention and control
184 groups at 6 months, and 3 out of 10 studies [21, 24, 45] at 12 months.

185 Eighteen studies [21-24, 26-32, 35, 39-41, 43, 45, 46] reported enough detail on
186 fat intake to allow meta-analysis at 3, 6, 12, 18, 24 and 36 months (Table 3). Consistent
187 decreases in fat intake in intervention compared with control groups with significant
188 SMDs at 3, 12, 18 and 24 months respectively. Heterogeneity was found at 3, 6, 12 and
189 24 months (I^2 59.9% – 93.1%). Most studies reported outcomes at 6 and 12 months
190 with 7 [21, 30, 35, 40, 43, 45, 46] out of 13 studies and 5 [22, 24, 27, 29, 40] out of 17
191 studies reporting significant between-group changes respectively. At 12 months one
192 study found a significant decrease in fat intake in the control group compared with the
193 intervention condition [35].

194 Eighteen studies [16, 22, 24, 26-31, 33-36, 38-40, 45, 46] reported PA outcomes
195 in enough detail to allow meta-analysis at 3, 6, 12, 18, 24 and 36 months (Table 3).
196 Positive SMDs were reported at all points in time with significant PA increases between
197 intervention compared with controls at 3, 6 and 12 months. Heterogeneity of trial
198 effects was found at 3, 6, 12 and 24 months (I^2 54.8 – 73%). The majority of studies
199 reported outcomes at 6 and 12 months with 7 [16, 30, 35, 39, 40, 43, 45] out of 12
200 studies, and 6 [27, 31, 36, 39, 40, 45] out of 10 studies respectively inducing significant
201 between-group PA differences.

202 *Dietary Interventions vs. Waiting List Control/Usual Care.* Four studies [17, 18, 32,
203 45] reported dietary outcomes which could be included in meta-analysis at 3, 6, 12 and
204 24 months (Table 3). Significant decreases in kilocalorie intake between intervention
205 and control groups were detected at 6, 12 and 24 months. Despite significant changes
206 in pooled outcomes at 12 months, only one study out of four [45] found a significant
207 between-group difference in kilocalorie intake.

208 Changes in fat intake were reported in enough detail by three studies [18, 45, 47]
209 to allow meta-analysis at 3, 6, 12, and 24 months (Table 3). Significant intervention
210 effects could be detected at 12 and 24. Heterogeneity was detected at 6 (I^2 = 76.1%)
211 and 12 (I^2 = 53.9%) months. Significant between-group changes in fat intake were
212 reported for all studies except one at 3 months [47] and one at 12 months [45]
213 respectively.

214 *PA Interventions vs. Waiting List Control/Usual Care.* Seven studies [15, 20, 30, 45,
215 50-52] reported PA change outcomes that allowed meta-analysis at 3, 6, 12 and 24
216 months. Significant SMDs were found at 6 and 12 months. At most time points

217 significant differences between intervention and control groups were reported with 2
218 [15, 52] out of 2 showing significant between-group PA differences at 3 months, and 3
219 [30, 45, 51] out of 5 at 6 months, and 2 [20, 45] out of 3 at 12 months.

220 *Intensive vs. Less Intensive Interventions.* Three studies [19, 47, 58] allowed the
221 investigation of an intensive against a less intensive D-only intervention. Meta-analysis
222 at 3 and 12 months revealed no significant changes in kilocalorie intake in the one study
223 including two samples providing enough details at those time points [19]. A significant
224 between-group difference in favour of the intensive intervention was reported in one of
225 the two samples. Changes in fat intake were reported to differ significantly in one study
226 consisting of two samples [19]. A further study of an intense dietary intervention
227 compared with a less intense one found no effects of changes in fat intake at 3 and 6
228 months [47].

229 Ten studies [25, 32, 36, 45, 46, 53-56, 58] allowed the investigation of an
230 intensive against a less intensive D-PA intervention. None of these studies reported
231 significant differences between groups for kilocalorie intake at any point in time.
232 Furthermore, only one intervention significantly changed fat intake at 6 and 18 months
233 [46], and one intervention significantly changed PA at 3 months [58] in favour of the
234 intensive intervention.

235 **Weight change**

236 -----Table 3 -----

237 -----Figure 2-----

238 *Diet and PA Interventions vs. Waiting List Control/Usual Care.* Twenty-five
239 [16, 21, 22, 24, 26-46] studies reported weight outcomes in sufficient detail to allow
240 meta-analysis at 3, 6, 12, 24 and 36 months (Table 2). At all time points weight
241 changes were significantly different between intervention and control groups with the
242 exception of 18 months. Effects at all points in time were heterogeneous ($I^2 = 68.3$ –
243 95.0%) with the exception of 24 months (Figure 2). Most studies reported outcomes at
244 6 and 12 months with 10 [21, 28, 30, 32, 35, 40, 42, 43, 45, 46] out of 15 at 6 months
245 and 8 [21, 24, 26, 27, 29, 32, 40, 45] out of 15 studies reporting significant between
246 group differences in weight respectively.

247 *Diet Interventions vs. Waiting List Control/Usual Care.* Six studies [18, 32, 45, 47-49]
248 reported changes in weight allowing meta-analysis at 3, 6, 12, and 24 months (Table 2).
249 Differences in weight loss between intervention and control groups were significant at

250 3, 6, and 12 months (Figure 2). Heterogeneity in the data was found at 3, 6, and 12
 251 months ($I^2 = 71.9\% - 84.8\%$).

252 *PA Interventions vs. Waiting List Control/Usual Care.* Seven studies [15, 20, 30, 45,
 253 50-52] reported weight outcomes that could be meta-analysed at 3, 6, 12 and 24 months
 254 (Table 2). The MD for weight change was significant only at six months with evidence
 255 for heterogeneity in the data ($I^2 = 83.5\%$). Few studies reported non-significant
 256 differences at 3, 12 and 24 months (Figure 2).

257 *Intensive vs. Less Intensive Interventions.* Eleven studies allowed comparisons between
 258 intensive and less intensive interventions [19, 25, 32, 36, 46, 47, 53-57] at various
 259 points in time. Intensive interventions, irrespective of whether the intervention
 260 consisted of a D-only or D-PA intervention, tended to induce greater MD for weight
 261 than the less intensive intervention groups (Table 2). Significant changes were noted at
 262 12 and 16 months for D-only and at 3 months for D-PA studies.

263 **Risk factor change**

264 -----Table 5-----

265 -----Table 6-----

266 -----Table 7-----

267 *Diet and PA Interventions vs. Waiting List Control/Usual Care.* Twenty studies [21,
 268 24, 26-33, 35-40, 42, 43, 45, 46] reported outcomes with respect to changes in at least
 269 one risk factor (Table 5). Most studies provided outcome data at 3, 6, 12 and 24
 270 months. Risk factor changes generally showed beneficial trends at various points in
 271 time. At 3 months significant changes were found in total cholesterol, triglycerides and
 272 SBP. At 6 months DBP, SBP and FBG showed significant improvements, with both
 273 SBP and DBP also showing significant differences between intervention and control
 274 groups at 12, 24 and 36 months. Furthermore, triglycerides as well as HbA1c showed
 275 improvements at 12 months. At 18 months LDL cholesterol was found to be
 276 significantly different in only one study [46] and at 24 months the only measure that
 277 was significantly improved was triglycerides. The only study reporting outcomes at 36
 278 months displayed significant HbA1c improvement [24]. Overall, significant
 279 improvements were found in all risk factors with the exception of HDL cholesterol.
 280 The most consistent improvements were found in SBP and triglycerides.

281 *Diet Interventions vs. Waiting List Control/Usual Care.* Five studies [18, 32, 45, 47,
 282 49] provided data for at least one risk factor, which could be analysed at 3, 6, 12 and 24
 283 months (Table 6). Risk factors generally showed tendencies towards improvement. At

284 3 months significant improvements occurred in total cholesterol, triglycerides and SBP.
285 SBP, DBP and FBG showed no significant differences compared with controls at 6
286 months (Table 6).

287 *PA Interventions vs. Waiting List Control/Usual Care.* Six studies [15, 20, 30, 45, 51,
288 52] reported risk factor outcomes at least once allowing meta-analysis at 3, 6, 12, and
289 24 months (Table 7). Changes in risk factors due to PA-only interventions were less
290 consistent when compared with D-PA and D-only interventions and no significant
291 effects could be detected.

292 *Effects of Intensive vs. Less Intensive Interventions.* Comparison of intensive and less
293 intensive interventions found a lack of significant differences with regard to risk factors.

294 DISCUSSION

295 The current systematic review assessed intervention effects on behaviour, as well as
296 weight and disease risk factors. When interpreting the results obtained in this review
297 shortcomings should be taken into account. Short-term outcomes (3 months) as well as
298 long-term outcomes (24 months onwards) are based on a limited number of studies.
299 Dietary and PA behaviours were reported using a variety of different measurements. In
300 particular, difficulties with self-reported outcomes and unreliable measures have been
301 highlighted in the literature before [8, 59] and might have had an impact on the current
302 findings. Analyses of D-only, PA-only, and intensive vs. less intensive interventions
303 were somewhat limited due to small number of studies which met inclusion criteria. It
304 should also be considered that some of our measures for heterogeneity were based on
305 few primary studies and this can reduce the clinical relevance of findings. The
306 methodological quality of some of the studies that met inclusion criteria displayed room
307 for improvement judged by study reportage. The majority of studies did not to report
308 on features such as the method of randomisation, or reasons for participant dropout.
309 Nearly half of the studies failed to report whether the analysis was intention-to-treat.
310 Blinding of outcome assessors was rarely described.

311 We were unable to determine which manipulations were the active and
312 successful ingredients within the studies [60]. We grouped the studies by their
313 behavioural targets but this does not specify how interventions successfully change
314 these behaviours and why some interventions were more effective than others [61].
315 More research is needed to determine which specific aspects of behavioural
316 interventions facilitate significant change in behaviour and subsequent physiological

317 outcomes, thereby explaining some of the significant heterogeneity typically
318 encountered in systematic review of behaviour interventions, including the current one.

319 The underlying model on the effect of behaviour change interventions postulates
320 that weight, disease risk factors and health are all influenced through mediating
321 behavioural effects [62]. To our knowledge this review is the first one to include
322 behavioural dietary and PA effects alongside weight and risk factor changes in obese
323 adults carrying additional risk factors. Results indicated that behavioural interventions
324 are successful at significantly changing behavioural outcomes to moderate degrees in
325 both dietary and PA behaviours over consistent periods of time. The magnitude of
326 behavioural effects was modest. The greatest reported reductions in MD of kilocalorie
327 intake for D-PA interventions and D-only interventions were -138 kcal and -360 kcal at
328 12 and 6 months respectively. Given that a common aim of many dietary
329 recommendations is the reduction of kilocalorie intake by 600 kilocalories per day, the
330 observed changes suggest that many participants struggled to adhere to dietary
331 prescriptions. Similar findings apply to modest dietary fat outcome effect sizes. A
332 previous systematic review in overweight/obese individuals without additional risk
333 factors found similarly modest significant effects of dietary advice on fibre, fat and
334 saturated fat intakes [8].

335 An interesting pattern emerges when comparing the magnitude of behavioural
336 intervention effects across different types of studies. Compared against respective
337 control conditions, behavioural D-PA study effects tended to be greater in magnitude in
338 studies aimed at changing either of the behaviours in isolation when compared with
339 studies that focused on diet and PA at the same time. This finding suggests that
340 behaviour change effects are greater when focusing on only one kind of behaviour, as
341 compared with both diet and PA behaviours at the same time. However, studies
342 focusing on dietary and PA behaviours simultaneously lead to greater long-term weight
343 loss than D-only or PA-only studies. It might be the case that changing two behaviours
344 at the same time decreases the magnitude of change due to participants' limited self-
345 regulatory resources [63]. However, longer-term behaviour change maintenance might
346 be upheld through focussing the attention and direction of behaviour change on both
347 behaviours that facilitate weight loss. Using dietary and PA interventions encourage a
348 coherent change in one's lifestyle behaviours towards behaving healthily.

349 Obtained weight loss findings are consistent with previous systematic reviews
350 [3, 12]. All types of studies successfully produced some weight loss in intervention

351 compared with control groups. Weight loss patterns over time in D-PA, D-only and
352 PA-only studies appeared to be similar. Greatest weight loss was found at six months,
353 with weight regain thereafter, echoing previous systematic review evidence [3] and
354 underlining the difficulty of permanent lifestyle change [64] in obese adults with
355 additional risk factors.

356 The magnitude of weight loss appeared to differ between intervention types.
357 Initial weight loss was greatest for D-only interventions, PA-only interventions showed
358 the weakest effects on weight, with the only significant effects found at 6 months.
359 Despite superior weight loss at 6 months by D-only interventions, subsequent time
360 points showed weight loss advantages in favour of a combination of diet and PA
361 interventions. After 12 months the only study type found to produce significant
362 differences in weight loss were interventions targeting changes in diet and PA.

363 Differences in magnitude of weight loss over time between interventions have
364 been documented by previous research. Avenell et al (2004) found that interventions
365 focusing on D-only led to greater MD in weight loss at 12 months compared with
366 studies that focused on both diet and PA, with a reverse of this trend at later time points.
367 Furthermore, a systematic review of RCTs of PA interventions found that the union of
368 PA with dietary interventions led to a significant increase in weight loss compared with
369 D-only interventions [65]. Previous literature has also indicated that PA-only typically
370 has not been significantly more effective than D-only interventions in short-term weight
371 loss [66]. These findings point to the importance of PA in the maintenance of initial,
372 dietary induced weight loss [64, 67]. Studies using more intensive interventions
373 produced greater weight loss. This is the case for D-PA, as well as for D-only
374 interventions.

375 Comparing the magnitude of weight lost in the current review to other published
376 meta-analyses with most trials not recruiting individuals carrying additional risk factors
377 [3, 12, 68, 68], it appears that the weight lost in our studies is less. This difference in
378 the magnitude of weight loss according to the criteria of additional risk factors holds
379 true for D-only interventions [12], PA-only interventions [65] and intensive compared
380 with less intensive interventions [69].

381 With regard to changes in disease risk factors, these displayed similar patterns to
382 weight loss outcomes. All types of interventions that could be compared with control
383 groups demonstrated a tendency towards improving various risk factors at some point in
384 time. However, the types of risk factors affected, as well as the magnitude and

385 consistency of risk factor change, tended to differ according to intervention type. D-
386 only interventions induced significant changes in total cholesterol, triglycerides, blood
387 pressure and FPG in intervention compared with control conditions. Overall, changes
388 tended to occur at 3 and 6 months, mirroring weight loss. Triglycerides seemed to show
389 consistent beneficial trends at all points in time. Similarly, total and LDL cholesterol
390 showed trends towards significant improvements at all time points for D-only
391 interventions. In comparison, PA-only interventions and intensive compared with less
392 intensive interventions were not successful at inducing risk factor changes.

393 The greatest changes in risk factors were achieved by interventions that targeted
394 both diet and PA. These changes tended to peak in magnitude at 12 months. Similar to
395 D-only interventions, triglycerides tended to show consistent positive improvements in
396 combination interventions. Furthermore, blood pressure seemed to show consistent and
397 mostly significant improvements over time. Unlike D-only interventions, the
398 combination of diet and PA induced significant improvements in HbA1c.

399 CONCLUSION

400 Overall, the findings of this systematic review extend the evidence of behaviour change
401 intervention effectiveness [8, 12, 70] and confirm the usefulness of this approach in
402 populations carrying additional risk factors. Improvements in behaviour, weight, and
403 disease risk factors were recorded for all types of reviewed behaviour change
404 interventions. Changes tended to be greatest at around 6 months. Behavioural changes
405 were modest and tended to be greater in studies focusing solely on a single behaviour
406 rather than both. Interventions focusing on diet and PA simultaneously showed the
407 greatest improvements in terms of weight loss and disease risk factor change. However,
408 most consistent beneficial effects over time regarding behaviour, weight and disease
409 risk factors were found in D-PA studies. The current review suggests that behavioural
410 interventions in at risk populations showed positive effect tendencies. Future research
411 should focus on identifying the most effective means of inducing dietary and PA
412 behaviour change.

413

414

Conflict of Interest statement

415 The authors declare that there are no conflicts of interest.

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Table 1 Details of included randomised controlled trials.

Study ID	Participants	Interventions	Outcomes
Argus-Collins 1997 [28]	Location: USA. Comorbidity: type 2 diabetes. Sex: 52 women, 12 men. Age mean(SD) years: (a) 62.4(5.9) (b) 61(5.7). BMI mean kg m-2: (a) 33.9 (b) 34.9. Weight mean(SD) kg: (a) 93.3(18.6) (b) 94.9(20.1).	(a) Group counselling intervention. <i>Diet</i> : <30% from fat, ~55-60% kcal from carbohydrate, 12-20% from protein. <i>Activity</i> : moderate physical activity ≥ 3 days/week. <i>Other</i> : weight loss of ≥ 4.5 kg at the rate of ≤ 0.9 /week. (b) Usual care. Allocated : (a) 32 (b) 32. % dropout : (a) 6.25% (b) 21.9% at 6 months. Possible comparisons : D-PA vs. UC.	Follow-up(s): 3 & 6 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, HbA1c, SBP, DBP, kcal, fat (% kcal), PASE.
Ash 2003 [17]	Location: Australia. Comorbidity: type 2 diabetes. Sex: all men. Age mean(SD) years: (a) 54.3(9.4) (b) 54.2(7.4) (c) 54.9(9.3). BMI mean(SD) kg m-2: (a) 31.2(3.4) (b) 31.1(3.7) (c) 32.7(2.4). Weight mean(SD) kg: (a) 96.7(11.4) (b) 97.2(13.5) (c) 101.4(11.9).	Prior to randomisation all patients underwent 2 weeks of dietary stabilisation (1400-1700 kcal/day, 50% kcal from carbohydrate, 30% kcal from fat). (a) Liquid meal replacement (Modifast). <i>Diet</i> : 1000 kcal/day on 4 days/week, 1400-1700 kcal/day on other three days. (b) Food provision. <i>Diet</i> : 6900 kJ/day (1650 kcal/day, 51% of energy from carbohydrate, 20% from protein and 29% from fat). (c) Usual care. Allocated : (a) 20 (b) 17 (c) 14. % dropout : 47.1% for all groups combined at 18 months. Possible comparisons : D vs. UC.	Follow-up(s): 12 weeks & 18 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, HbA1c, kcal.
Blonk 1994 [53]	Location: Holland. Comorbidity: type 2 diabetes. Sex: (a) 18 women, 9 men (b) 16 women, 10 men. Age mean(CI) years: (a) 59.0(42.0, 69.0) (b) 58.5(29.0, 70.0). BMI mean(CI) kg m-2: (a) 31.3(27.2, 44.3) (b) 32.8(27.9-45.8). Weight mean(CI) kg: (a) 92.3(69.3, 120.8) (b) 87.8(65.2, 158.3).	(a) Comprehensive program. <i>Diet</i> : 500kcal deficit, minimum intake of 1000 kcal, 30% kcal from fat, 50-55% kcal from carbohydrate, 25g fiber, <300mg/day cholesterol, and 15% kcal from protein. <i>Activity</i> : scheduled exercise sessions twice/week fading out over time. (b) Conventional programme. <i>Diet</i> : same as (a) <i>Activity</i> : scheduled exercise sessions and exercise every day at home and increase in regular daily activities. Allocated : (a) 27 (b) 26. % dropout : not given. Possible comparisons : Intensive vs. less intensive (D-PA).	Follow-up(s): 2, 4, 6, 8, 12, 14, 16, 18, 20, 22 & 24 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, HbA1c, SBP, DBP, kcal.
Blumenthal 2000 [30]	Location: USA. Comorbidity: hypertension. Sex: (a) 34 women, 21 men (b) 29 women, 25 men (c) 11 women, 13 men. Age mean(SD) years: (a) 48.5(1.2) (b) 46.6(1.2) (c) 47.2(1.8). BMI mean(SD) kg m-2: (a) 32.1(4.0) (b) 32.8(4.0) (c) 32.6(5.1). Weight mean(SD) kg: (a) 93.3(17.7) (b) 95.4(14.5) (c) 94.0(17.3).	(a) Weight management group. <i>Diet</i> : 5021J (1200 kcal) for women, 6276J (1500 kcal) for men, 15-20% of energy from fat. <i>Activity</i> : scheduled and supervised exercise sessions 4-5 times/week <i>Other</i> : 0.5-1kg weight loss/week. (b) Exercise group. <i>Activity</i> : same as weight management group (c) Waiting list control group. Allocated : (a) 55 (b) 54 (c) 24. % dropout : (a) 16% (b) 19% (c) 8% at 6 months. Possible comparisons : D-PA vs. WLC; PA vs. WLC.	Follow-up(s): 6 months. Outcomes: weight, SBP, DBP, FPG, kcal, fat (g), treadmill time.
Burke 2007	Location: Perth, Australia.	(a) Lifestyle programme. <i>Diet</i> : DASH diet low in fat (<30% kcal from fat, 10%	Follow-up(s): 4 & 12

Study ID	Participants	Interventions	Outcomes
[29]	Comorbidity: hypertension (drug treated) Sex: (a) 67 women 56 men (b) 67 women, 51 men Age mean(SD) years: (a) 57.1(7.2) (b) 55.5(7.5) BMI mean (SD) kg m-2: (a) 30.4(2.9) (b) 29.7(2.5) Weight mean(SD) kg: (a) 86.7(12.4) (b) 84.2(10.8)	kcal from saturated fat), > fruit & vegetables, < salt & sugar, ≥ 4 fish meals/week, ≤ two standard drinks/day. <i>Activity</i> : accumulate ≥30 min of MIPA on most days, increase incidental activity. <i>Other</i> : decrease baseline weight by 5-10% over 4 months. (b) Usual care. Allocated : (a) 123 (b) 118 % dropout : (a) 17% (b) 24% Possible comparisons : D-PA vs. UC.	months Outcomes: weight, SBP, DBP, kcal, fat (% kcal), time spent in PA (min/week).
Carels. 2004 [54]	Location: USA. Comorbidity: postmenopause. Gender: all female. Age mean(SD) years: (a) 55.1(8.3) (b) 54.3(7.8). BMI mean kg m-2: (a) 37.8(5.8) (b) 35.1(5).	(a) Lifestyle change. <i>Diet & Activity</i> : LEARN program recommendations [71]. (b) Lifestyle change + Self-control skills. <i>Diet & Activity</i> : same as (a) (only behavioural techniques differ). Allocated : (a) 21 (b) 23. % dropout : (a) 14.3% (b) 17.4% at 12 months. Possible comparisons : Intensive vs. less intensive (D-PA).	Follow-up(s): 6 & 12 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, SBP, DBP, FPG, kcal, fat (% kcal), treadmill time (sec).
Clark 2004 [22]	Location: UK. Comorbidity: type 2 diabetes. Sex: 42 women, 58 men. Age mean years: 59.5. BMI mean (SD) kg m-2: (a) 32.40(4.49) (b) 31.30(5.01). Weight mean(SD) kg: not given.	(a) Lifestyle intervention. <i>Diet</i> : Self selected goal(s) for lifestyle change. <i>Activity</i> : Self selected goal(s) for lifestyle change. (b) Usual care group. Allocated : (a) 50 (b) 50. % dropout : (a) 8% (b) 4% at 52 weeks. Possible comparisons : D-PA vs. UC.	Follow-up(s): 3 & 12 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, HbA1c, FHQ (Block fat screener), PASE.
Deakin 2006 [31]	Location: UK. Comorbidity: type 2 diabetes. Sex: 152 women, 162 men. Age mean(SD) years: (a) 61.3(9.7) (b) 61.8(11.0). BMI mean(SD) kg m-2: (a) 30.8(5.3) (b) 30.6(5.7). Weight mean(SD) kg: (a) 83.2(14.5) (b) 82.8(17.6).	(a) X-PERT programme. <i>Diet</i> : Recommendations based on the British Nutrition Foundation's 'Balance of Good Health'. <i>Activity</i> : Exercise on prescription scheme (individual exercise recommendations from GP). (b) Control group. Allocated : (a) 157 (b) 157. % dropout : (a) 4.5% (b) 10.2%. Possible comparisons : D-PA vs. UC.	Follow-up(s): 4 & 14 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs., HbA1c, SBP, DBP, kcal, fat (% kcal), Summary of self care activity (PA).
Diabetes Prevention Program, 2003 [21]	Location: USA. Comorbidity: elevated fasting and post-load plasma glucose concentrations. Sex: (a) 737 women, 345 men (b) 710 women, 363 men (c) 747 women, 335 men. Age mean(SD) years: (a) 50.6(11.3) (b) 50.9(10.3) (c) 50.3(10.4). BMI mean(SD) kg m-2: (a) 33.9 (6.8) (b) 33.9(6.6) (c)	(a) Lifestyle intervention. <i>Diet</i> : 500-1000 kcal/day deficit, 25% kcal from fat. <i>Activity</i> : ≥700 kcal/week (equivalent to 150min of MPA). <i>Other</i> : 7% weight loss of initial body weight. (b) Metformin group. <i>Other</i> : 850mg of metformin daily. (c) Placebo control group. Allocated : (a) 1079 (b) 1073 (c) 1082. % dropout : "92.5% of participants had attended a scheduled visit within previous six months".	Follow-up(s): 6, 12, 18, 24, 30, 36, 42, & 48 months. Outcomes: weight, HbAc1, FPG, kcal, fat (% kcal).

Study ID	Participants	Interventions	Outcomes
Djuric 2002 [32]	<p>34.2(6.7). Weight mean(SD) kg: (a) 94.1(20.8) (b) 94.3(19.9) (c) 94.3(20.2). Location: USA. Comorbidity: breast cancer. Sex: all women. Age mean(SD) years: 51.7(8.4). BMI mean(SD) kg m-2: (a) 35(1.2) (b) 35.5(1.1) (c) 36.8 (8) (d) 34.9(1.2). Weight mean(SD) kg: (a) 95.5(5) (b) 91.4(2.7) (c) 100.5(5) (d) 95(3.6).</p>	<p>Possible comparisons: D-PA vs. UC.</p> <p>(a) Weight watchers group. <i>Diet:</i> Weight Watchers prescriptions. (b) Individualised group. <i>Diet:</i> 500-1000kcal/d deficit, 20-25% kcal from fat. <i>Activity:</i> 30-45 min/d of MPA most days. <i>Other:</i> decrease of 10% of baseline weight over 6 months. (c) Comprehensive group. <i>Diet:</i> Weight Watchers prescriptions. <i>Activity:</i> 30-45 min/d of MPA most days. <i>Other:</i> decrease of 10% of baseline weight over 6 months. (d) Control group. Allocated: (a) 11 (b) 13 (c) 11 (d) 13. % dropout: (a) 27.3% (b) 30.8% (c) 9.1% (d) 7.7% at 12 months. Possible comparisons: D-PA vs. UC., Intensive vs. less intensive (D-PA, D only) (a) Personal Health Planning group. <i>Diet & Activity:</i> change of behaviours linked to cardiovascular risk (e.g. “focus of commitment to healthier behaviours” or “education on the topics of nutrition, PA...”). (b) Control group. Allocated: (a) 77 (b) 77. % dropout: (a) 27.3% (b) 14.3% at 10 months. Possible comparisons: D-PA vs. UC.</p>	<p>Follow-up(s): 3, 6, & 12 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, FPG, kcal, fat (% kcal).</p>
Edelman 2006 [33]	<p>Location: USA. Comorbidity: One or more of the following: diabetes, hypertension, dyslipidemia, smoking, or BMI >25 anthropometric measurements. Sex: 124 women, 30 men. Age mean(SD) years: (a) 52.2(5.2) (b) 53.4(4.8). BMI mean(SD) kg m-2: (a) 33.3(7.8) (b) 34.1(7.7). Weight mean(SD) kg: not given.</p>	<p>(a) Exercise intervention. <i>Activity:</i> graduated, low-level exercise ≥ 4 times/week. (b) Control group. Allocated: (a) 53 (b) 51. % dropout: (a) 5.7% (b) 10.52% at 6 months. Possible comparisons: PA vs. UC.</p>	<p>Follow-up(s): 5 & 10 months. Outcomes: weight, SBP, DBP, lipid profiles, days of exercise/week.</p>
Evangelista 2006 [50]	<p>Location: USA. Comorbidity: advanced heart failure. Sex: (a) 11 women, 37 men (b) 17 women, 34 men. Age mean(SD) years: (a) 53(13) (b) 55(12). BMI mean(SD) kg m-2: 30.5(4.2). Weight mean(SD) kg: 92.8(13.5).</p>	<p>(a) Lifestyle intervention. <i>Diet:</i> <30 % kcal from fat, <10 kcal from saturated fat, ≥ 15 g/1000kcal from fibre. <i>Activity:</i> MIPA ≥ 30 min/day. <i>Other:</i> weight reduction $\geq 5\%$. (b) Control group. Allocated: (a) 265 (b) 257. % dropout: (a) 12.8% (b) 21% at 3 years. Possible comparisons: D-PA vs. UC.</p>	<p>Follow-up(s): 6 months. Outcomes: weight, walking test (min/minute).</p>
Finish Diabetes Prevention Study, 2003 [24]	<p>Location: Finland. Comorbidity: impaired glucose tolerance. Sex: (a) 176 women, 81men (b) 174 women, 91 men. Age mean(SD) years: (a) 55 (7) (b) 55(7). BMI mean(SD) kg m-2: (a) 31.4(4.5) (b) 31.1(4.5). Weight mean(SD) kg: (a) 86.7(14.0) (b) 85.5 (14.4).</p>	<p>(a) Telephone follow-up + Community resource group. <i>Diet:</i> feedback on current dietary behaviour.</p>	<p>Follow-up(s): 12 & 36 months. Outcomes: weight, total cholesterol, HDL, TGs, HbA1c, FPG, kcal, fat (% kcal), LTPA (min/week).</p>
Glasgow 2000 [47]	<p>Location: USA. Comorbidity: type 2 diabetes.</p>	<p>(a) Telephone follow-up + Community resource group. <i>Diet:</i> feedback on current dietary behaviour.</p>	<p>Follow-up(s): 3 & 6 months.</p>

Study ID	Participants	Interventions	Outcomes
	Sex: (a) 45 women, 35 men (b) 46 women, 34 men (c) 38 women, 42 men, (d) 53 women, 27 men. Age mean(SD) years: (a) 57.4(9.4) (b) 59.0(9.6) (c) 60.5(8.6) (d) 60.6(9.5). BMI mean kg m-2: (a) 31.23 (b) 33.27 (c) 34.37 (d) 34.69. Weight mean(SD) kg: (a) 90.26 (b) 96.16 (c) 99.33 (d) 100.24.	(b) Telephone follow-up group. <i>Diet:</i> same as (a) (c) Community resource group. <i>Diet:</i> same as (a) (d) Basic group. <i>Diet:</i> same as (a) Allocated: (a) 80 (b) 80 (c) 80 (d) 80. % dropout: (a) 16.25% (b) 16.25% (c) 6.25% (d) 85% at 6 months. Possible comparisons: D vs. UC; Intensive vs. less intensive (D only).	Outcomes: weight, total cholesterol, HbA1c, kcal, fat Block Fat Screener.
Glasgow 1996 [48]	Location: USA. Comorbidity: type 1 or type 2 diabetes. Sex: (a) 60 women, 38 men (b) 68 women, 40 men. Age mean(SD) years: (a) 61.7(12.1) (b) 63.1(10.5). BMI mean kg m-2: (a) 30.4 (b) 30.2. Weight mean(SD) kg: not given.	(a) Intervention. <i>Diet:</i> ≤30% calories from fat, ≤10% kcal from saturated fat. (b) Control group. Allocated: (a) 106-108 (b) 94-98. % dropout: (a) 16.7% (b) 15.3% at 12 months. Possible comparisons: D only vs. UC.	Follow-up(s): 3 & 12 months. Outcomes: weight, total cholesterol, HbA1c, kcal, fat (% kcal).
Goodrick 1998 [34]	Location: USA. Comorbidity: binge eating disorder. Sex: all women. Age mean(SD) years: (a) 89.04(10.15) (b) 87.71(9.58) (c) 86.49(9.83). BMI mean(SD) kg m-2: (a) 33.50(3.46) (b) 33.16(3.21) (c) 32.22(2.97). Weight mean(SD) kg: (a) 89.04(10.15) (b) 87.71(9.58) (c) 86.49(9.83).	(a) Dieting treatment. <i>Diet:</i> reducing fat (40 g/day), increasing complex carbohydrates, and eating a variety of foods. <i>Activity:</i> 4 to 5hr/week at an intensity based on training heart rate. <i>Other:</i> weight loss averaging 1lb (0.454kg)/wk. (b) Non-dieting treatment. <i>Diet:</i> “gradual reductions of fat without feelings of deprivation”. <i>Activity:</i> home-based walking program with gradually attained goal of 4-5 h/week. (c) Control group. Allocated: (a) 79 (b) 78 (c) 62. % dropout: (a) 15.2% (b) 16.7% (c) 6.5% at 18 months for (a) and (b) and 6 months for (c). Possible comparisons: D-PA vs. UC.	Follow-up(s): 6 & 18 months. Outcomes: weight, kcal/kg/day.
Grilo. 2005 [25]	Location: USA. Comorbidity: Binge Eating Disorder. Sex: (a) 29 women, 9 men (b) 32 women, 5 men. Age mean(SD) years: (a) 46.0(9.2) (b) 46.0(9.2) (c) 48.0(8.2). BMI mean(SD) kg m-2: (a) 36.0(6.6) (b) 33.4(5.7) (c) 36.2(6.6). Weight mean(SD) kg: not given.	(a) Behavioural weight loss. <i>Diet:</i> LEARN Program for Weight Management [71] <i>Activity:</i> LEARN Program for Weight Management [71] (b) Cognitive behavioural therapy. <i>Diet:</i> Overcoming Binge Eating [72] <i>Activity:</i> Overcoming Binge Eating [72] (c) Control. Allocated: (a) 38 (b) 37 (c) 15 % dropout: (a) 34% (b) 13% (c) 13% Possible comparisons: Intensive vs. less intensive (D-PA).	Follow-up(s): 3 months. Outcomes: weight.
Hardcastle 2007 [35]	Location: UK. Comorbidity: CHD risk factors (hypertension, hypercholesterolemia) Sex: 240 women, 118 men.	(a) Counselling intervention. <i>Diet:</i> individualised depending on readiness to change. <i>Activity:</i> individualised depending on readiness to change. (b) Control group. Allocated: (a) 203 (b) 131.	Follow-up(s): 6 months. Outcomes: weight, total cholesterol, LDL, HDL, triglycerides, SBP,

Study ID	Participants	Interventions	Outcomes
Jehn 2006 [23]	Age mean(SD) years: (a) 50.1(10.5) (b) 50.41(10.8) BMI mean(SD) kg m-2: (a) 33.67(5.4) (b) 34.28(7.0) Weight mean(SD) kg: (a) 93.7(17.1) (b) 91.73(17.2) Location: USA. Comorbidity: hypertension. Sex: (a) 13 women, 9 men (b) 16 women, 7 men. Age mean(SD) years: (a) 53(11) (b) 54(8). BMI mean(SD) kg m-2: (a) 32.8(5.4) (b) 34.2(3.2). Weight mean(SD) kg: (a) 92.0(14.6) (b) 97.0 (20.9).	% dropout: (a) 38.4% (b) 29% Possible comparisons: D-PA vs. UC. (a) Lifestyle group. <i>Diet:</i> food provision of DASH diet (18% kcal protein, 55% kcal carbohydrate, 27% kcal fat) <i>Activity:</i> 30-45 minutes of supervised, MIPA, 3 days/week. <i>Other:</i> weight loss goal of 4.5kg after 9 weeks. (b) Control group. Allocated: (a) 22 (b) 23. % dropout: (a) 14 % (b) 0%. Possible comparisons: D-PA vs. UC.	DBP, fat (% kcal fat), overall PA (met/min/week). Follow-up(s): 12 months. Outcomes: weight, fat (% kcal).
Jones et al. 2003 [49]	Location: Canada. Comorbidity: type 1 or type 2 diabetes. Sex: (a) 233 women, 277 men (b) 257 women, 262 men. Age mean(SD) years: (a1) 54.58 (a2) 55.12 (b1) 54.86 (b2) 54.60. BMI mean kg m-2: (a1) 31.98 (a2) 32.22 (b1) 31.43 (b2) 31.59. Weight mean(SD) kg: not given.	(a1) Intervention. <i>Diet:</i> healthy eating focusing on dietary fat reduction. <i>Other:</i> smoking cessation and regular blood glucose monitoring (free strips for self-testing provided). (a2) Intervention. <i>Diet:</i> healthy eating focusing on dietary fat reduction. <i>Other:</i> smoking cessation and regular blood glucose monitoring (no strips for self-testing provided). (b1) Control group. <i>Other:</i> free strips for self-testing provided. (b2) Control group. Allocated: (a1) 260 (a2) 250 (b1) 269 (b2) 250. % dropout: 33% overall at 12 months. Possible comparisons: D only vs. UC.	Follow-up(s): 12 months. Outcomes: weight, fat (% kcal).
Keyserling 2002 [36]	Location: USA. Comorbidity: type 2 diabetes. Sex: all female. Age mean years: (a) 58.5 (b) 59.8 (c) 59.2. BMI mean kg m-2: (a) 36.2 (b) 34.6 (c) 36.2. Weight mean kg: (a) 95 (b) 91.9 (c) 95.7.	(a) Clinic & Community intervention. <i>Diet:</i> 2-3 dietary goals selected according to dietary risk assessment. <i>Activity:</i> 2-3 activity goals selected according to PA assessment. (b) Clinical intervention. <i>Diet:</i> 2-3 same as (a) <i>Activity:</i> same as (a) (c) Control group. Allocated: (a) 67 (b) 66 (c) 67. % dropout: (a) 19.4% (b) 10.6% (c) 14.9% at 12 months. Possible comparisons: D-PA vs. UC; Intensive vs. less intensive (D-PA).	Follow-up(s): 6 & 12 months. Outcomes: weight, total cholesterol, HDL, HbA1c, kcal, kcal expended/day.
Kirk 2004 [51]	Location: UK. Comorbidity: type 2 diabetes. Sex: 35 women, 35 men. Age mean(SD) years: 57.6(7.9). BMI mean(SD) kg m-2: 34.6(6.8). Weight mean(SD) kg: not given.	(a) Exercise intervention. <i>Activity:</i> accumulate 30 min of MIPA most days of the week. (b) Control group. Allocated: (a) 35 (b) 35. % dropout: (a) 11.4% (b) 8.6% at 6 months. Possible comparisons: PA only vs. UC.	Follow-up(s): 6 months. Outcomes: weight, LDL, HDL, TGs, HbA1c, SBP, DBP, Activity counts.
Kirkman 1994 [37]	Location: USA. Comorbidity: type 2 diabetes. Sex: 3 women, 272 men.	(a) Intervention group. <i>Diet & Activity:</i> prescriptions from GP (not specified) to improve glycemic control. (b) Control group.	Follow-up(s): 12 months. Outcomes: weight, total

Study ID	Participants	Interventions	Outcomes
Laitinen 1993 [26]	Age mean(SD) years: (a) 63.9 (8.6) (b) 63.2 (8.3). % above ideal weight(SD): (a) 130.6(23.8) (b) 130.6(193.2). Weight mean(SD) kg: not given. Location: Finland. Comorbidity: type 2 diabetes. Sex: 49 women, 37 men. Age mean(SD) years: (a) 52.2(7) (b) 54.2(6.5). BMI mean(SD) kg m-2: (a) 33.95(5.3) (b) 33.5(4.7).	Allocated: (a) 204 (b) 71. % dropout: not given. Possible comparisons: D-PA vs. UC. (a) Intervention group. <i>Diet:</i> planned energy restriction, ≤ 30% kcal from fat, ≤10% of kcal saturated fat, ≤300 mg/day dietary cholesterol, fatty acids ≥20% of energy unsaturated fat, and increase carbohydrates (e.g. fruits, berries, and vegetables). <i>Activity:</i> increase frequency of exercise sessions to 3-4/week, lasting 30-60 min each. <i>Other:</i> weight reduction, normoglycemia, correction of dyslipidemias, and normalisation of elevated blood pressure. (b) Usual care group. Allocated: (a) 40 (b) 46. % dropout: (a) 5% (b) 4% at 15 months. Possible comparisons: D-PA vs. UC.	cholesterol, LDL, HDL, TGs. Follow-up(s): 3, 15 & 24 months. Outcomes: weight, total cholesterol, HDL, TGs, HbA1c, FPG, kcal, fat (% kcal fat).
Logue, 2004 [55]	Location: USA. Comorbidity: Hypertension, elevated blood cholesterol, (oesteo)arthritis, diabetes. Sex: (a) 232 women, 97 men (b) 226 women, 110 men. Number of patients within age range(%) years: 40 to 49: (a) 138(42) (b) 129(42); 50 to 59 (a) 138(42) (b) 141(42); 60 to 69 (a) 52(16) (b) 66(20). Number of patients within BMI range(%): 25 to 29.9 (a) 59(18) (b) 73(22); 30 to 34.5 (a) 119(37) (b) 107(32); 35 to 39 (a) 69(21) (b) 82(24); 40+ (a)79(24) (b) 74(22). Weight mean(SD) kg: not given.	(a) Intervention group. <i>Diet:</i> increase dietary portion control, <dietary fat, >fruits & vegetables. <i>Activity:</i> increase exercise, increase usual activity. (b) Augmented usual care. <i>Diet & Activity:</i> prescriptions by dietitian based on diet and activity recalls. Allocated: (a) 329 (b) 336. % dropout: (a) 37.8% for weight, 20.08% for other information (b) 31.3% for weight, 17.6% for other information at 24 months. Possible comparisons: Intensive vs. less intensive (D-PA).	Follow-up(s): 6, 12, 18, & 24 months. Outcomes: weight, SBP, DBP, blood lipids, kcal, kcal/kg/day.
Mefferd 2007 [38]	Location: USA. Comorbidity: Breast cancer. Sex: (a) 56 Women (b) 29 women. Age mean(SD) years: 56.3(8.2). BMI mean(SD) kg m-2: 31.0(4.2). Weight mean(SD) kg: 84.7(12.6)	(a) Intervention group. <i>Diet:</i> 500-1000 kcal/d deficit. Activity: one h/d of moderate to vigorous PA. (b) Control group. Allocated: (a) 56 (b) 29. % dropout: (a) 16% (b) 0%. Possible comparisons: D-PA vs. UC.	Follow-up(s): 4 months. Outcomes: weight, total cholesterol, HDL, TGs, moderate + vigorous PA.
Menard 2005 [39]	Location: Canada. Comorbidity: type 2 diabetes. Sex: (a) 9 women 27 men (b) 14 women 22 men. Age mean(SD) years: (a) 55.9(8.6) (b) 53.7(7.5). BMI mean (SD) kg m-2: (a) 32.6(5.7) (b) 32.9(5.5). Weight mean(SD) kg: (a) 93.5(20.1) (b) 88.5(18.5).	(a) Intervention group. <i>Diet:</i> 50-55% kcal from carbohydrates, ≤30% kcal fat, ≤10% kcal from saturated fat. <i>Activity:</i> home based exercise sessions, 3-4 times/week, 45-55 minutes, intensity at 50-80% of maximum heart rate. <i>Other:</i> After 3 months pharmacological therapy was introduced in patients not able to reach treatment goals (b) Control group.	Follow-up(s): 6, 12 & 18 months. Outcomes: weight, LDL, HDL, TGs, HbA1c, SBP, DBP, FPG, kcal, fat (g),

Study ID	Participants	Interventions	Outcomes
Metz. 2000 [18]	<p>Location: USA.</p> <p>Comorbidity: 1. hypertension/dyslipidemia or 2. type 2 diabetes.</p> <p>Sex: 1. hypertension/dyslipidemia: (a) 50 women, 43 men (b) 50 women 40 men</p> <p>2. type 2 diabetes: (a) 31 women, 25 men (b) 38 women, 25 men.</p> <p>Age mean(SD) years: 1. hypertension/dyslipidemia: (a) 54.5(9.0) (b) 54.4(9.5) 2. type 2 diabetes: (a) 54.6(9.0) (b) 54.0(9.9).</p> <p>BMI mean (SD) kg m-2: 1. hypertension/ dyslipidemia: (a) 33.0(4.9) (b) 32.0(4.2), 2. type 2 diabetes: (a) 33.0(4.4) (b) 34.5(4.5).</p> <p>Weight mean(SD) kg: not given.</p>	<p>Allocated: (a) 36 (b) 36.</p> <p>% dropout (a) 16.7% (b) 19.5% at 18 months.</p> <p>Possible comparisons: D-PA vs. UC.</p> <p>(a) Intervention group. <i>Diet:</i> 22% kcal from fat, 58% kcal from carbohydrates, 20% kcal from protein.</p> <p>(b) Usual care group.</p> <p>Allocated: 1 Hypertension/dyslipidemia: (a) 93 (b) 90, 2. type 2 diabetes: (a) 56 (b) 63.</p> <p>% dropout : 1. hypertension/dyslipidemia: (a) 15.1% (b) 12.2% at 52 weeks, 2. Type 2 diabetes: (a) 26.8% (b) 19.0% at 52 weeks.</p> <p>Possible comparisons: D only vs. UC.</p>	<p>METs.</p> <p>Time of measurements: 12, 26 & 52 weeks.</p> <p>Outcomes: weight, total cholesterol, LDL HDL, TGs, HbA1c, SBP, DBP, FPG, kcal, fat (% kcal).</p>
Oldroyd 2006 [40]	<p>Location: UK</p> <p>Comorbidity: impaired glucose tolerance.</p> <p>Sex: (a) 19 women, 16 men (b) 10 women, 22 men.</p> <p>Age mean(CI) years: (a) 58.2(41, 75) (b) 57.5(41, 73).</p> <p>BMI mean (SD) kg m-2: (a) 30.4(5.6) (b) 29.9 (4.9).</p> <p>Weight mean(SD) kg: (a) 83.3(16.6) (b) 85.5(14.2).</p>	<p>(a) Intervention group. <i>Diet:</i> 30% kcal from fat, polysaturated to saturated fat ratio of 1.0, 50-55% kcal from carbohydrate, 20g/1000kcal of fibre <i>Activity:</i> 20-30 min of aerobic activity for 2-3 times/week.</p> <p>(b) Control group.</p> <p>Allocated: (a) 39 (b) 39.</p> <p>% dropout: (a) 38.5% (b) 23.1% at 24 months.</p> <p>Possible comparisons: D-PA vs. UC.</p>	<p>Follow-up(s): 6, 12 & 24 months.</p> <p>Outcomes: weight, total cholesterol, LDL, HbA1c, FPG, kcal, fat (g), % engaging in regular PA.</p>
Pascale, 1995 [19]	<p>Location: USA.</p> <p>Comorbidity: 1. type 2 diabetes or 2. family history of diabetes.</p> <p>Sex: all women.</p> <p>Age mean(SD) years: 1. type 2 diabetes: 56.4(8.4), 2. family history of type 2 diabetes: 42.7(8.4).</p> <p>BMI mean kg m-2: 1. type 2 diabetes (a) 36.4(4.7) (b) 36.3(4.2), 2. family history of type 2 diabetes (a) 35.0(4.4) (b) 36.1(5.6).</p> <p>Weight mean(SD) kg: 1. type 2 diabetes (a) 93.1(13.0) (b) 94.4(9.5), 2. family history of type 2 diabetes (a) 95.3(13.3) (b) 94.5(14.6).</p>	<p>(a) CAL restriction group. <i>Diet:</i> 1000-1500 kcal/day, 30% of kcal from fat.</p> <p>(b) CAL + fat restriction group. <i>Diet:</i> same as (a).</p> <p>Allocated: 1. type 2 diabetes: (a) 22 (b) 22, 2. family history of type 2 diabetes: (a) 23 (b) 23.</p> <p>% dropout: 1. type 2 diabetes: (a) 27% (b) 32%, 2. family history of type 2 diabetes: (a) 43% (b) 30% at 12 months.</p> <p>Possible comparisons: Intensive vs. less intensive (D only).</p>	<p>Follow-up(s): 16 weeks, & 12 months.</p> <p>Outcomes: weight, total cholesterol, HDL, LDL, TGs, HbA1c, kcal, fat (%kcal).</p>
Pendelton, 2002	<p>Location: Brisbane, Queensland, Australia.</p> <p>Comorbidity: binge eating disorder.</p>	<p>(a) CBT group. <i>Diet:</i> “establish regular and healthy eating patterns”.</p> <p>(b) CBT & Exercise group. <i>Diet:</i> same as (a). <i>Activity:</i> exercise three</p>	<p>Follow-up(s): 4, 10, & 16 months.</p>

Study ID	Participants	Interventions	Outcomes
[58]	Sex: all women. Age mean(SD) years: 45(8.3). BMI mean(SD) kg m-2: 36.2(6.5). Weight mean(SD) kg: 97.2(17.8).	times/week \geq 45 min/session. (c) CBT & Maintenance. <i>Diet</i> : same as (a). (d) CBT & Exercise & maintenance. <i>Diet</i> : same as (a). <i>Activity</i> : same as (b). Allocated : (a) 28 (b) 27 (c) 24 (d) 31. % dropout : (a) 39.3% (b) 25.9% (c) 16.7% (d) 22.6% at 16 months. Possible comparisons : Intensive vs. less intensive (D-PA).	Outcomes: weight.
PREMIER trial, 2003 [46]	Location: USA. Comorbidity: hypertension. Sex: (a) 174 women, 94 men (b) 154 women, 115 men (c) 172 women, 101 men. Age mean(SD) years: (a) 50.2(8.6) (b) 50.2(9.3) (c) 49.5(8.8). BMI mean(SD) kg m-2: (a) 33.0(5.5) (b) 33.3(6.3) (c) 32.9(5.6). Weight mean(SD) kg: not given.	(a) Established group. <i>Diet</i> : \leq 100 mmol/day of dietary sodium, intake of \leq 30 ml/day alcohol for men and 15 ml/day for women. <i>Activity</i> : at least 180 minutes/week of MIPA. <i>Other</i> : weight loss of \geq 6.8 kg if BMI \geq 25 kg/m ² . (b) Established + DASH diet. <i>Diet</i> : same as (a) plus \leq 7% kcal from saturated fat, \leq 25% of kcal from fat. <i>Activity</i> : \geq 180 minutes/week of MIPA. <i>Other</i> : same as (a) (c) Advice only group. <i>Diet</i> : reduced-sodium diet. <i>Activity</i> : engaging in regular MIPA. Allocated : (a) 268 (b) 269 (c) 273. % dropout : (a) 6% (b) 6% (c) 0% at 18 months. Possible comparisons : D-PA vs. UC, Intensive vs. less intensive (D-PA)	Follow-up(s): 6 & 18 months. Outcomes: weight, DBP, SBP, kcal, fat (% kcal), kcal/kg.
Reeves 2001 [41]	Location: USA. Comorbidity: binge eating disorders Sex: all female. Number of patients within age range(%) years: (a) 27-39: n=14, 40-45: n=19, 46-50: n=13 (b) 27-39: n=9, -45: n=14, 46-50: n=13. BMI mean kg m-2 (b) 33.8: (a) 31.8. Weight mean(SD) kg: (a) 89.36(9.53) (b) 86.64(14.52).	(a) Intervention group. <i>Diet</i> : decrease fat intake. <i>Activity</i> : five 45-minute walking sessions/week. (b) Waiting list control group. Allocated : (a) 59 (b) 39. % dropout : (a) 28.3% (b) 7.7% at 6 months. Possible comparisons : D-PA vs. WLC.	Follow-up(s): 6 months. Outcomes: weight, kcal, fat (% kcal).
Samaras 1997 [20]	Location: Australia. Comorbidity: type 2 diabetes. Sex: (a) 9 women, 4 men (b) 7 women, 6 men. Age mean(SE) years: (a) 60.5(7.8) (b) 60.5(2.1). BMI mean(SE) kg m-2: (a) 32.3(1.1) (b) 35.7(1.6). Weight mean(SD) kg: (a) 83.0(3.6) (b) 98.2(3.4).	(a) Intervention group. <i>Activity</i> : monthly one hour aerobic exercise classes. (b) Usual care control group. Allocated : (a) 13 (b) 13. % dropout : (a) 0% (b) 0% at 12 months.	Follow-up(s): 6 & 12 months. Outcomes: weight, total cholesterol, HDL, TGs, HbA1c, FPG, METs.
Southard 2003 [42]	Location: Canada. Comorbidity: Cardiovascular disease. Sex: (a) 17 women, 36 men (b) 9 women, 42 men. Age mean(SD) years: (a) 61.8(10.8) (b) 62.8(10.6). BMI mean(SD) kg m-2: (a) 31.1(6.8) (b) 29.2(4.8). Weight mean(SD) kg: (a) 89 (b) 91.99.	(a) Special intervention. <i>Diet</i> : dietician feedback to dietary practice. <i>Activity</i> : individual instructions by case managers. (b) Usual care. Allocated : (a) 53 (b) 51. % dropout : (a) 6% (b) 2%. Possible comparisons : D-PA vs. WLC.	Follow-up(s): 6 months. Outcomes: weight, total cholesterol, HDL, LDL, TGs, SBP, DBP, MEDFICTS (indicating fat intake), minutes of weekly exercise.

Study ID	Participants	Interventions	Outcomes
Tate, 2003 [56]	Location: USA. Comorbidity: one or more other risk factors for type 2 diabetes. Sex: (a) 42 women, 4 men (b) 41 women, 5 men. Age mean(SD) years: (a) 49.8(9.3) (b) 47.3(9.5). BMI mean(SD) kg m-2: (a) 32.5(3.5) (b) 33.7(3.7). Weight mean(SD) kg: (a) 86.2(14.3) (b) 89.4(12.6).	(a) Internet counselling group. <i>Diet:</i> 1200 to 1500kcal, 20% kcal from fat. <i>Activity:</i> ≥ 1000 kcal/wk of PA. (b) Basic internet program. <i>Diet:</i> same as (a). <i>Activity:</i> same as (a). Allocated: (a) 46 (b) 46. % dropout: (a) 0% (b) 0% at 12 months. Possible comparisons: Intensive vs. less intensive (D-PA)	Follow-up(s): 12 months. Outcomes: weight, FPG, fat (% kcal).
Tessier 2000 [15]	Location: Canada. Comorbidity: type 2 diabetes. Sex: (a) 7 women, 12 men (b) 9 women, 11 men. Age mean(SD) years: (a) 69.3(4.2) (b) 69.5(5.1). BMI mean(SD) kg m-2: (a) 29.4(3.7) (b) 30.7(5.4). Weight mean(SD) kg: (a) 79.4(14.3) (b) 83.1(18.0)	(a) Physical exercise programme. <i>Activity:</i> exercise group sessions, three times/week, for 16 weeks. (b) Control group. Allocated: (a) 19 (b) 20. % dropout: (a) 21% (b) 5%. Possible comparisons: PA only vs. UC	Follow-up(s): 4 months. Outcomes: weight, HbA1c, treadmill test (min).
Tudor-Locke 2004 [52]	Location: Canada. Comorbidity: type 2 diabetes. Sex: (a) 12 women, 12 men (b) 9 women, 14 men. Age mean(SD) years: (a) 52.8(5.7) (b) 52.5(4.8). BMI mean(SD) kg m-2: (a) 34.1(6.1) (b) 32.5(5.0).	(a) Intervention group. <i>Activity:</i> self selected activity goals. (b) Waiting list control group. Allocated: (a) 30 (b) 30. % dropout: (a) 33% (b) 4% at 24 weeks. Possible comparisons: PA only vs. WLC	Follow-up(s): 16 & 24 weeks. Outcomes: weight, SBP, DBP, total cholesterol, LDL HDL TGs, HbA1c, FPG, steps/day.
Toobert 2000 [27]	Location: USA. Comorbidity: coronary heart disease Sex: all women. Age mean(SD) years: (a) 64(10) (b) 63(11). BMI mean(SD) kg m-2: (a) 32(4.2) (b) 32 (5.5). Weight mean(SD) kg: (a) 80(10) (b) 79(15).	(a) Intervention group. <i>Diet:</i> Reversal diet: <10% kcal from fat, 70 to 75% kcal from carbohydrates, 15 to 20% kcal from protein, 5 mg of cholesterol/day. <i>Activity:</i> 1 h/day, ≥ 3 days each week. (b) Control group. Allocated: (a) 16 (b) 12. % dropout: (a) 12.5% (b) 8.3% at 24 months. Possible comparisons: D-PA vs. WLC	Follow-up(s): 4, 12 and 24 months. Outcomes: weight, total cholesterol, LDL HDL, TGs, SBP, DBP, kcal, fat (% kcal), Summary of self care activity (PA).
Toobert 2005 [43]	Location: USA. Comorbidity: type 2 diabetes. Sex: all women. Age mean(SD) years: (a) 61.1(8.0) (b) 60.7(7.8). BMI mea (SD) kg m-2: (a) 35.1(7.7) (b) 35.6(8.8). Weight mean(SD) kg: (a) 92.3(21.2) (b) 93.9(23.8).	(a) Mediterranean Lifestyle Program. <i>Diet:</i> more bread; more root vegetables, green vegetables, and legumes; more fish; less red meat (e.g., beef, lamb, pork), to be replaced by poultry; daily fruit; and avoidance of butter and cream, to be replaced by olive/canola oil or olive-/canola-based margarine. <i>Activity:</i> 30 min of MIPA on most days of the week, once accomplished, 1 hr of MIPA/day. (b) Usual care. Allocated: (a) 163 (b) 116. % dropout: 12% after 6 months. Possible comparisons: D-PA vs. UC	Follow-up(s): 6 months. Outcomes: weight, total cholesterol, LDL, HDL, TGs, Hba1c, SBP, DBP, METs x duration x days baseline adjusted.
Villareal	Location: USA.	(a) Intervention group. <i>Diet:</i> ≈ 750 kcal/d deficit, ≈ 30 kcal from fat, 50% kcal	Follow-up(s): 6 months.

Study ID	Participants	Interventions	Outcomes
2006 [16]	Comorbidity: Metabolic syndrome. Sex: (a) 12 women, 5 men (b) 6 women, 4 men. Age mean(SD) years: (a) 69(5) (b) 71(4). BMI mean(SD) kg m-2: (a) 39(5) (b) 39(5). Weight mean(SD) kg: (a) 100(14) (b) 103(20).	from carbohydrate, 20% kcal from protein. <i>Activity</i> : Exercise-training on 3 days/week for 90 min. <i>Other</i> : 1.5% loss of body weight/week, 10% weight loss after 6 months. (b) Control group. Allocated : (a) 17 (b) 10. % dropout : (a) 12% (b) 10%. Possible comparisons : D-PA vs. WLC	Outcomes: weight, LDL, walking speed (m/min).
Wing 1985 [44]	Location: USA. Comorbidity: type 2 diabetes. Sex: 33 women, 20 men. Age mean(SE) years: 55.1(7.28). BMI mean(SE) kg m-2: 34.8(5.10). Weight mean(SE) kg: 96.4(2.3).	(a) Behaviour modification condition. <i>Diet</i> : self-selected kcal goals, <four servings of high sugar foods/week, > fiber intake. <i>Activity</i> : 1000 kcal expenditure/week. (b) Nutrition education condition. <i>Diet</i> : "...given calorie goal at a level comparable to [...] the behaviour modification condition". (c) Standard care condition. Allocated : 53 overall. % dropout : 6% overall at 62 weeks. Possible comparisons : D-PA vs. WLC	Follow-up(s): 3 & 12 months. Outcomes: weight, total cholesterol, HDL, TGs, SBP, DBP, FPG.
Wing, 1991 [57]	Location: USA. Comorbidity: type 2 diabetes. Age mean(SD) years: (a) 51.2(7.3) (b) 53.6(7.7). BMI mean(SD) kg m-2: (a) 36.64(5.77) (b) 35.68(5.76). Weight mean(SD) kg: (a) 102.97(18.5) (b) 96.84(19.69).	(a) Alone condition. <i>Diet</i> : 1,200-1,500 kcal/day. <i>Activity</i> : 1,000 kcal/week expenditure through exercise. <i>Other</i> : weight loss reward: \$2for every lb lost. (b) Together condition. <i>Diet</i> : same as (a). <i>Activity</i> : same as (a) <i>Other</i> : same as (a). Allocated : (a) 25 (b) 24. % dropout : (a) 8% (b) 17% at 12 months. Possible comparisons : Intensive vs. Less intensive (D-PA).	Follow-up(s): 20 weeks, 12 months. Outcomes: weight, HbA1c, FPG.
Wing 1998 [45]	Location: USA. Comorbidity: family history of type 2 diabetes. Sex: 122 women, 32 men. Age mean(SD) years:: (a) 45.0(4.7) (b) 46.4(4.5) (c) 46.3(3.8) (d) 45.3(4.9). BMI mean(SD) kg m-2: (a) 36.1(4.1) (b) 36.0(3.7) (c) 35.7(4.1) (d) 36.0 (5.4). Weight mean(SD) kg: (a) 99.6 (13.0) (b) 99.3(15.3) (c) 98.7(15.9) (d) 97.4(16.0).	(a) Diet condition. <i>Diet</i> : 800-1000 kcal/day, 20% of kcal from fat, gradually made more flexible with calorie goals of 1200-1500 kcal/day. (b) Exercise condition. <i>Activity</i> : gradual increase activity to 1500 kcal/week through 5 days/week, increases of 250 kcal/week. (c) Diet-plus-exercise condition. <i>Diet</i> : same as (a). <i>Activity</i> : same as (b). (d) Usual care Allocated : (a) 37 (b) 37 (c) 40 (d) 40. % dropout : (a) 5% (b) 16% (c) 20% (d) 23% at 24 months. Possible comparisons : D-PA vs. UC, D only vs. UC, PA only vs. UC	Follow-up(s): 6, 12, & 24 months. Outcomes: weight, LDL, HDL, TGs, HbA1, SBP, DBP FPG, kcal, fat (% kcal), kcal/week.

Note. D-PA = Diet & PA intervention, D only = diet only intervention, DBP = diastolic blood pressure, FHQ = Food Habit Questionnaire, FPG = fasting plasma glucose, HbA1c = haemoglobin A1C, HDL = High-density lipoprotein cholesterol, Kcal – kilocalories, LDL = Low-density lipoprotein cholesterol, LTPA = leisure time physical activity, min = minutes, METs = metabolic equivalent of task, MIPA = moderate intensity physical activity, PA only = Physical activity only interventions, PASE = physical activity scale for the elderly, SBP = systolic blood pressure, TGs = tryglycerides, UC = Usual care, WLC = Waiting list control.

Table 2 Intervention effects (95% CIs) on calorie intake, fat intake and PA in diet and PA, diet only and PA only interventions at 3, 6, 12, 18, 24, and 36 months.

Month	Diet + PA						Diet only				PA only	
	kcal intake		Fat intake		PA		kcal intake		Fat intake		PA	n _s
	MD	CI	SMD	CI	SMD	CI	MD	CI	SMD	CI	SMD	CI
3	-11.6	-160, 137	-0.5**	-0.9, -0.2	0.5**	0.3, 0.8	-15	-382, 352	0	-0.3, 0.4	0.8**	-0.1, 1.6
6	-100**	-238, 39	-0.5**	-0.9, 0	0.3**	0.1, 0.6	-360	-656, -64	-0.4**	-1.0, 0.2	0.7*	0.4, 0.9
12	-138	-190, -86	-0.3**	-0.5, -0.2	0.5**	0.2, 0.7	-266	-389, -143	-0.6**	-0.9, -0.2	0.7	0.4, 1.1
24	-116*	-264, 32	-1.0**	-1.7, -0.4	0.4**	0, 0.8	-519	-811, -227	-0.8	-1.3, -0.3	0.2	-0.3, 0.7
36	-107	-196, -18	-0.2	-0.4, 0	0.0	-0.2, 0.2	no data		no data		no data	

Note: I^2 * >25%, ** >50%, kcal = kilocalorie, MD = mean difference, SMD = standardised mean difference, CI = confidence interval.

N studies (participants) for MD kcal intake in D-PA trials: 4 (530), 8 (990), 10 (3418), 3 (140), and 1 (434) at 3, 6, 12, 24, and 36 months.

N studies (participants) for SMD in fat intake in D-PA trials: 5 (624), 9 (1469), 11 (3514), 3 (142), and 1 (434) at 3, 6, 12, 24, and 36 months.

N studies (participants) for SMD for PA in D-PA trials: 6 (705), 12 (1757), 10 (1484), 4 (576), and 1 (434) at 3, 6, 12, 24, and 36 months.

N studies (participants) for MD kcal intake in D-only trials: 1 (31), 1 (67), 5 (336), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for SMD in fat intake in D-only trials: 1 (67), 3 (298), and 1 (66) at 6, 12, and 24 months.

N studies (participants) for SMD in PA in PA-only trials: 2 (86), 5 (303), 3 (142), and 1 (62) at 3, 6, 12, and 24 months.

Table 3 Mean differences (95% CIs) in weight changes from meta-analyses of RCTs comparing diet and PA, diet only and PA only interventions against usual care or waiting list control groups, and RCTs comparing intensive diet and PA, and intensive diet only interventions against less intensive diet and PA and less intensive diet only interventions.

Month	Diet & PA		Diet only		PA only		Intensive diet & PA		Intensive diet	
	MD	CI	MD	CI	MD	CI	MD	CI	MD	CI
3	-2.8**	-4.4, -1.2	-2.9**	-4.7, -1.2	-0.1	-2.0, 1.8	-1.3	-2.4, -0.2	-1.2**	-2.7, 0.3
6	-3.5**	-5.1, -1.9	-4.0**	-6.7, -1.2	-2.7**	-4.8, -0.6	-0.9*	-1.7, 0.0	0	-2.0, 2.0
12	-2.9**	-4.3, -1.5	-2.3**	-3.8, -0.8	-0.3	-2.2, 1.6	-1.2*	-2.7, 0.4	-3.1	-5.5, -0.6
24	-2.8	-3.5, -2.0	-1.8	-4.8, 1.2	1.3	-1.0, 3.6	-0.3	-1.4, 0.7	No data	
36	-2.6	-3.6, -1.6	No data		No data		No data		No data	

Note: I^2 * >25%, ** >50%, MD = mean difference, CI = confidence interval.

N studies (participants) for diet and PA trials: 8 (850), 15 (4056), 15 (4048), 3 (572), 6 (730) and 1 (434) at 3, 6, 12, 18, 24, and 36 months

N studies (participants) for D-only trials: 4 (450), 6 (486), 6 (1107), and 1 (66) at 3, 6, 12 and 24 months.

N studies (participants) for PA-only trials: 2 (86), 5 (319), 2 (83), and 1 (62) at 3, 6, 12 and 24 months.

N studies (participants) for intensive diet and PA trials: 5 (264), 7 (1323), 7 (750), 4 (957), and 2 (488) at 3, 6, 12, 18 and 24 months.

N studies (participants) for intensive D-only trials: 4 (246), 1 (147), 3 (100), and 1 (40) at 3, 6, 12 and 24 months.

Table 5 Mean differences (95% CIs) of total cholesterol (mmol/l), LDL cholesterol (mmol/l) HDH cholesterol (mmol/l), triglycerides (mmol/l), glycosylated haemoglobin (HbA1c), blood pressure (mmHg) and glucose (mmol/l) changes over time from meta-analyses of D-PA interventions

Outcome	3 months		6 months		12 months		24 months		36 months	
	MD	CI	MD	CI	MD	CI	MD	CI	MD	CI
Cholesterol	-0.3	-0.4, -0.1	-0.1*	-0.3, 0.1	-0.1*	-0.3, 0.0	-0.1	-0.2, 0.0	-0.2	-0.4, 0.0
LDL cholesterol	-0.1	-0.2, 0.1	-0.1	-0.2, 0.0	-0.2**	-0.3, 0.0	0.1	-0.1, 0.2	No	data
HDL cholesterol	0.0	-0.1, 0.0	0.0	0.0, 0.0	0.0	0.0, 0.0	0.0	0.0, 0.1	0.0	0.0, 0.1
Triglycerides	-0.2	-0.4, -0.1	-0.1*	-0.3, 0.0	-0.3**	-0.5, -0.1	-0.2	-0.4, -0.1	-0.1	-0.2, 0.0
HbA1c%	-0.8	-1.9, 0.3	-0.2*	-0.5, 0.1	-0.2	-0.4, -0.1	0.0	-0.2, 0.2	-0.2	-0.3, -0.1
DBP	-1.9	-3.3, -0.6	-2.5	-3.3, -1.6	-2.5	-3.2, -1.9	-2.7	-3.5, -1.9	-3.25	-4.4, -2.1
SBP	-5.0	-7.0, -2.9	-4.6**	-6.8, -2.4	-3.7*	-5.1, -2.2	-3.0	-4.1, -1.9	-2.7	-4.1, -1.3
FPG	0.0	-1.0, 1.0	-0.4	-0.5, -0.2	0.1**	-0.3, 0.2	0.1**	-0.5, 0.4	-0.1	-0.2, 0.0

Note: I^2 * >25%, ** >50%, MD = mean difference, CI = confidence interval, LDL cholesterol = low density lipoprotein cholesterol, HDL cholesterol = high density lipoprotein cholesterol, DBP = diastolic blood pressure, SBP = systolic blood pressure, FPG = fasting plasma glucose.

N studies (participants) for total cholesterol: 5 (700), 7 (1017), 10 (1537), 5 (730), and 1 (434) at 3, 6, 12, 24 and 36 months.

N studies (participants) for LDL cholesterol: 5 (698), 6 (897), 8 (900), and 3 (430) at 3, 6, 12, , 24 months.

N studies (participants) for HDL cholesterol: 5 (700), 7 (1014), 10, (1532), 1 (63), and 1 (434) at 3, 6, , 24, 36 months.

N studies (participants) for HbA1c: 2 (359), 5 (583), 6 (1123), 1 (61), 2 (113), and 1 (459) at 3, 6, 12, 24, and 36 months.

N studies (participants) for triglycerides: 5 (701), 6 (898), 9 (1430), 4 (676), and 1 (434) at 3, 6, 12, , 24, and 36 months.

N studies (participants) for DBP: 4 (587), 7 (1166), 9 (3462), 4 (2303), and 1 (2161) at 3, 6, 12, , 24, and 36 months.

N studies (participants) for SBP: 4 (587), 7 (1175), 9 (3462), 4 (2303), and 1 (2161) at 3, 6, 12, , 24, and 36 months.

N studies (participants) for FBP: 1 (241), 3 (198), 6 (804), (3 (623), and 1 (434) at 3, 6, 12, , 24, and 36 months.

Table 6 Mean difference (95% CIs) of total cholesterol (mmol/l), LDL cholesterol (mmol/l) HDH cholesterol (mmol/l), triglycerides (mmol/l), glycosylated haemoglobin (HbA1c), blood pressure (mmHg) and glucose (mmol/l) changes over time from meta-analyses of D-only interventions

Outcome	3 months		6 months		12 months		24 months	
	MD	CI	MD	CI	MD	CI	MD	CI
Cholesterol	-0.3	-0.4, -0.2	-0.3**	-0.6, 0.1	-0.1**	-0.4, 0.2	-0.3	-0.6, 0.0
LDL cholesterol	-0.1	-0.3, 0.0	-0.1**	-0.4, 0.3	-0.1**	-0.5, 0.3	-0.2	-0.5, 0.1
HDL cholesterol	0.0	-0.03, 0.02	0.0**	-0.1, 0.1	0.1	0.0, 0.1	0.0	-0.1, 0.1
Triglycerides	-0.3*	-0.6, -0.1	-0.3	-0.5, 0.0	-0.1	-0.4, 0.2	-0.3	-1.3, 0.6
HbA1c%	-0.2**	-0.5, 0.1	-0.3**	-0.7, 0.0	-0.1	-0.2, 0.0	0.00	-0.2, 0.2
DBP	-0.8	-2.2, 0.5	-1.8	-3.5, -0.1	-0.9	-2.4, 0.5	1.0	-2.8, 4.8
SBP	-2.9	-5.1, -0.7	-4.2	-7.9, -0.5	-0.3	-2.9, 2.3	0.7	-4.6, 6.0
FPG	-0.8	-2.0, 0.4	-0.3	-0.5, -0.1	-0.3	-1.1, 0.5	0.1	-0.3, 0.5

Note: I^2 * >25%, ** >50%, MD = mean difference, CI = confidence interval, LDL cholesterol = low density lipoprotein cholesterol, HDL cholesterol = high density lipoprotein cholesterol, DBP = diastolic blood pressure, SBP = systolic blood pressure, FPG = fasting plasma glucose.

N studies (participants) for total cholesterol: 3 (458), 3 (329), 5 (496), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for LDL cholesterol: 2 (185), 3 (329), 4 (332), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for HDL cholesterol: 2 (285), 3 (325), 4, (332), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for triglycerides: 2 (285), 3 (329), 4 (332), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for HbA1c: 4 (602), 4 (464), 3 (411), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for DBP: 2 (285), 3 (360), 3 (312), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for SBP: 2 (285), 3 (360), 3 (312), and 1 (66) at 3, 6, 12, and 24 months.

N studies (participants) for FBP: 2 (285), 3 (329), 4 (332), and 1 (66) at 3, 6, 12, and 24 months.

Table 7 Mean difference (95% CIs) of total cholesterol (mmol/l), LDL cholesterol (mmol/l) HDH cholesterol (mmol/l), triglycerides (mmol/l), glycosylated haemoglobin (HbA1c), blood pressure (mmHg) and glucose (mmol/l) changes over time from meta-analyses of PA-only interventions

Outcome	3 months		6 months		12 months		24 months	
	MD	CI	MD	CI	MD	CI	MD	CI
Cholesterol	0.1	-0.3, 0.5	-0.1	-0.2, 0.2	-0.1	-0.4, 0.2	0.2	-0.1, 0.4
LDL cholesterol	0.0	-0.3, 0.3	-0.1	-0.3, 0.1	-0.1	-0.4, 0.1	0.2	-0.1, 0.5
HDL cholesterol	0.1	-0.1, 0.2	0.1	0.0, 0.2	0.1	0.0, 0.1	0.0	-0.1, 0.1
Triglycerides	0.0	-0.9, 0.9	-0.1	-0.6, 0.4	0.0	-0.4, 0.4	-0.2	0.8, 0.5
HbA1c%	0.0	-1.7, 1.6	-0.2	-0.6, 0.1	-0.1	-0.8, 0.5	0.0	-0.2, 0.2
DBP	0.4	-3.6, 4.4	-1.7	-4.6, 1.2	-4.0	-8.7, 0.7	0.0	-4.0, 4.0
SBP	-1.7	-7.9, 4.6	-3.1	-7.7, 1.74	0.0	-6.8, 6.8	2.4	-4.1, 8.7
FPG	0.7	-0.4, 1.8)	-0.1	-0.4, 0.2	0.0	-0.3, 0.3	0.2	-0.2, 0.6

Note: I^2 * >25%, ** >50%, MD = mean difference, CI = confidence interval, LDL cholesterol = low density lipoprotein cholesterol, HDL cholesterol = high density lipoprotein cholesterol, DBP = diastolic blood pressure, SBP = systolic blood pressure, FPG = fasting plasma glucose.

N studies (participants) for total cholesterol: 1 (47), 3 (138), 3 (147), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for LDL cholesterol: 1 (47), 2 (105), 2 (113), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for HDL cholesterol: 1 (47), 3 (134), 3 (143), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for triglycerides: 1 (47), 3 (137), 2 (147), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for HbA1c: 1 (39), 3 (141), 2 (91), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for DBP: 1 (47), 3 (196), 1 (57), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for SBP: 1 (47), 3 (196), 1 (57), and 1 (62) at 3, 6, 12, and 24 months.

N studies (participants) for FBP: 1 (47), 2 (91), 2 (85), and 1 (62) at 3, 6, 12, and 24 month.

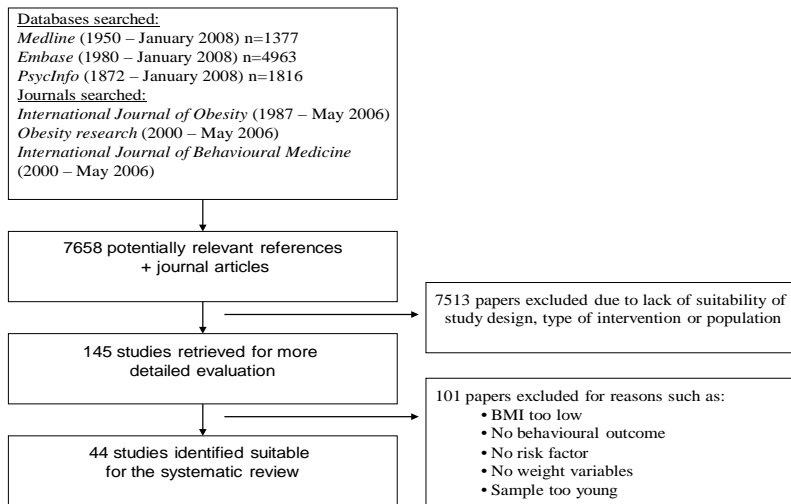


Figure 1: Flow diagram for locating RCTs for systematic review

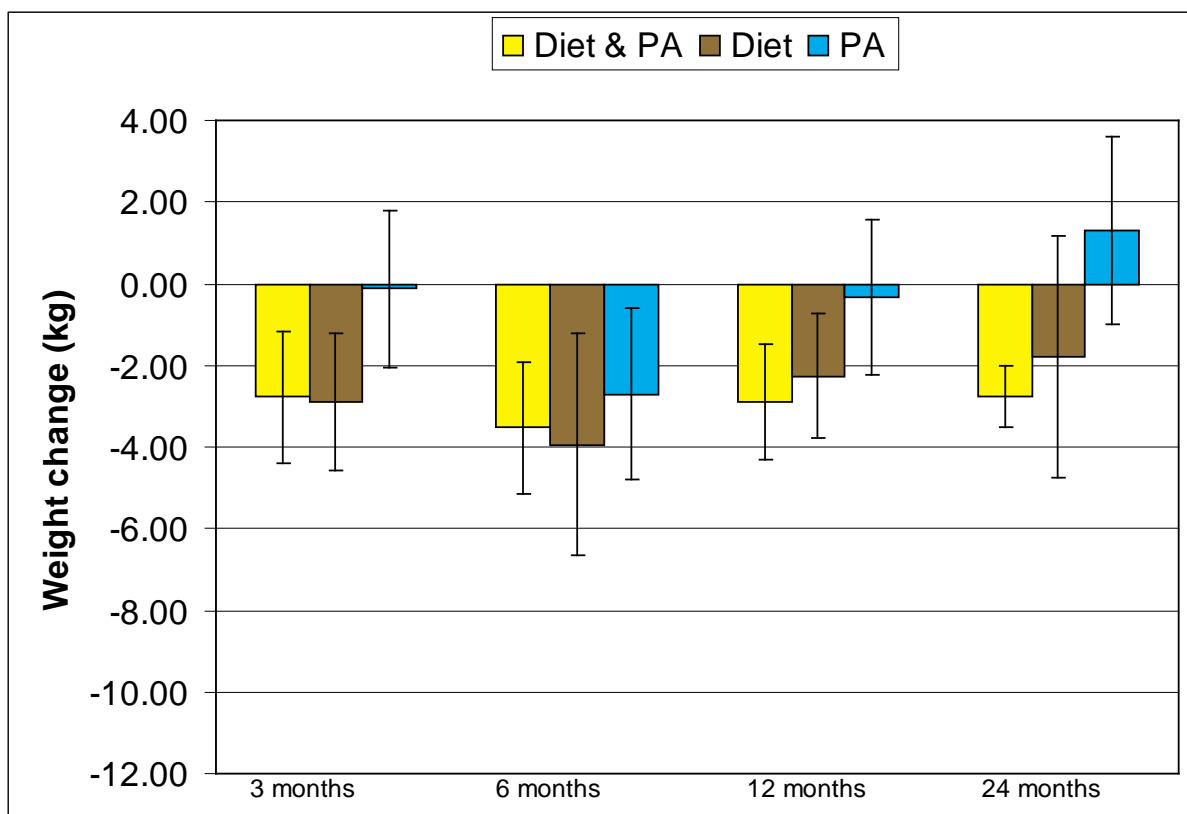


Figure 2: MD in weight change between intervention and control participants for diet and PA, D-only and PA-only interventions at 3, 6, 12, and 24 months.